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PATENT
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IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant:	Keiko NERIISHI et al.	Conf.:	6258
Appl. No.:	09/749,791	Group:	1655
Filed:	December 28, 2000	Examiner:	Chakrabarti
For:	DNA DETECTION DEVICE		

AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

June 5, 2002

Sir:

In response to the Office Action mailed December 5, 2001, the period for response having been extended three months to expire on June 5, 2002 the following amendments and remarks are respectfully submitted in connection with the above-identified application.

IN THE CLAIMS

Please cancel claims 4 and 5 without prejudice or disclaimer of the subject matter contained therein.

Please amend claim 1 as follows:

Claim 1 (Amended) A process for detecting a complementary DNA fragment which comprises the steps of:

A1

bringing single-stranded sample DNA fragments having a radioactive label in a liquid phase into contact with a DNA micro-array having a support and at least two defined areas in each of which a group of probe compounds selected from the group

consisting of DNA molecules, DNA fragments, synthesized oligonucleotides, synthesized polynucleotides, and PNA are fixed under such condition that a group of the probe compounds fixed in one area differs from a group of the probe compounds fixed in another area, so that DNA fragments complementary to a group of the probe compounds are fixed by hybridization to the area in which the last-mentioned group is fixed;

removing unfixed sample DNA fragments from the DNA micro-array;

keeping the DNA micro-array in contact with a radiation image storage panel containing a stimulable phosphor in areas corresponding to the areas on which groups of the probe compounds are fixed, so that the corresponding areas of the stimulable phosphor sheet can absorb and store radiation energy of the radioactive label coming from the DNA fragments fixed to the DNA micro-array;

irradiating the radiation image storage panel with a stimulating light, so that the image storage panel releases a stimulated emission from the area in which the radiation energy is stored;

detecting the stimulated emission photoelectrically to obtain a series of electric signals; and

processing the electric signals to locate the area in which the complementary DNA fragments are fixed.

Claim 2 (Amended) The process of claim 1, in which area on the radiation image storage panel other than the area of stimulable phosphor is covered by a physical barrier member made of non-radiation transmitting material selected from the group consisting of metal, ceramic material, and polymer material.

A1

Please add the following new claims:

-6. A process for detecting a complementary DNA fragment which comprises the steps of:

bringing single-stranded sample DNA fragments having a radioactive label in a liquid phase into contact with a gridded DNA micro-array on a solid support having at least two defined areas in each of which a group of probe compounds selected from the group consisting of DNA molecules, DNA fragments, synthesized oligonucleotides, synthesized polynucleotides, and PNA are fixed under such condition that a group of the probe compounds fixed in one area differs from a group of the probe compounds fixed in another area, so that DNA fragments complementary to a group of the probe compounds are fixed by hybridization to the area in which the probe compounds are fixed;

A2

removing unfixed sample DNA fragments from the DNA micro-array;

keeping the DNA micro-array in contact with a radiation image storage panel containing a stimulable phosphor in areas corresponding to the areas on which groups of the probe compounds are fixed, so that the corresponding areas of the stimulable

phosphor sheet can absorb and store radiation energy of the radioactive label coming from the DNA fragments fixed to the DNA micro-array;

irradiating the radiation image storage panel with a stimulating light, so that the image storage panel releases a stimulated emission from the area in which the radiation energy is stored;

detecting the stimulated emission photoelectrically to obtain a series of electric signals; and

processing the electric signals to locate the area in which the complementary DNA fragments are fixed.

7. The process of claim 2, wherein the material is selected from the group consisting of stainless steel, aluminum, copper, brass, aluminum oxide, magnesium oxide, silicon nitride, carbon, polyethylene terephthalate, polyethylene naphthalate, polyurethane and acrylic resin.

REMARKS

STATUS OF THE CLAIMS

Claims 1-3, 6 and 7 are pending in the present application. Claims 4 and 5 have been cancelled without prejudice or disclaimer of the subject matter contained therein. Support for the amendments to claim 1 includes the description at page 8, lines 5-8 of the specification (e.g. "nucleotide derivatives and/or analogues thereof"). The basis for the DNA micro-array having a support includes the description on page 5, lines 24-25

of the specification. The basis for claim 7 and the amendments to claim 2 includes the description of the non-radiation transmitting material at page 6, lines 2-9 of the specification. Claim 6 is supported by amended claim 1 and by Fig. 1.

ELECTION/RESTRICTION

Restriction to one of the inventions of Group I, claims 1-3, drawn to a process for detecting a complementary DNA fragment by hybridization, and Group II, claims 4 and 5, drawn to a kit, has been required by the Examiner under 35 U.S.C. 121. In response, Applicants hereby affirm the election of claims 1-3 in order to initiate prosecution in the present application, without traverse. Claims 4-5 have been cancelled without prejudice or disclaimer of the subject matter contained therein.

REJECTION OF CLAIMS 1-3 UNDER 35 U.S.C. 112 (PARAGRAPHS 6 AND 7 OF OFFICE ACTION)

Claims 1-3 have been rejected by the Examiner under 35 U.S.C. 112, second paragraph, for the reasons set forth in paragraphs 6-7 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The phrase "nucleotide derivatives and analogues thereof" in claim 1 has been cancelled in favor of the definition of the same phrase at page 8, lines 2-8 of the specification. The Examiner refers Applicants to the definition of the phrase "nucleotide derivatives or analogues" on page 8, line 6+ of the specification

and indicates that the definition is not ordinary usage. That is, the Examiner alleges that the ordinary meaning of this phrase is that of the Ward reference, which teaches 7-deazapurine linkages. However, the specification defines "nucleotide derivatives or analogues" to permit simply ordinary DNA fragments to fall within the scope of the phrase. As indicated in the specification, Applicants intend to permit simply ordinary DNA fragments to fall within the scope of the phrase as discussed on page 8, line 6+ of the specification. Thus, the phrase should not be narrowly construed.

With respect to claim 2, the phrase "barrier member" has been amended to read "physical barrier member" made of non-radiation transmitting material selected from the group consisting of metal, ceramic material, and polymer material.

In view of the amendments to the claims, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, second paragraph, are respectfully requested.

REJECTION OF CLAIMS 1-3 UNDER 35 U.S.C. 102(e) (PARAGRAPHS 8 AND 9 OF OFFICE ACTION); REJECTION OF CLAIMS 1-3 UNDER 35 U.S.C. 103(a) (PARAGRAPHS 10 AND 11 OF OFFICE ACTION)

Claims 1-3 have been rejected by the Examiner under 35 U.S.C. 102(e) over U.S. Patent 6,256,405 to Some et al. for the reasons set forth in paragraphs 8 and 9 of the Office Action. Claims 1-3 have been rejected by the Examiner under 35 U.S.C. 103(a) over Some et al. in view of U.S. Patent 6,271,002B1 to Linsley et al. in view of U.S. Patent 4,711,955 to Ward et al.

for the reasons set forth in paragraphs 10 and 11 of the Office Action. These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

The present invention as recited in claim 1, as amended, relates to a process for detecting a complementary DNA fragment which comprises the steps of bringing single-stranded sample DNA fragments having a radioactive label in a liquid phase into contact with a DNA micro-array having a support and at least two defined areas in each of which a group of probe compounds selected from the group consisting of DNA molecules, DNA fragments, synthesized oligonucleotides, synthesized polynucleotides, and PNA are fixed under such condition that a group of the probe compounds fixed in one area differs from a group of the probe compounds fixed in another area, so that DNA fragments complementary to a group of the probe compounds are fixed by hybridization to the area in which the last-mentioned group is fixed; removing unfixed sample DNA fragments from the DNA micro-array; keeping the DNA micro-array in contact with a radiation image storage panel containing a stimulable phosphor in areas corresponding to the areas on which groups of the probe compounds are fixed, so that the corresponding areas of the stimulable phosphor sheet can absorb and store radiation energy of the radioactive label coming from the DNA fragments fixed to the DNA micro-array; irradiating the radiation image storage panel with a stimulating light, so that the image storage panel releases a stimulated emission from the area in which the

radiation energy is stored; detecting the stimulated emission photoelectrically to obtain a series of electric signals; and processing the electric signals to locate the area in which the complementary DNA fragments are fixed.

Applicants respectfully submit that the Examiner misunderstands a characteristic feature of the invention, that is, the construction of the radiation image storage panel employed in the claimed process. Specifically, see the step of "keeping the DNA micro-array in contact with" which further recites" a radiation image storage panel containing a stimulable phosphor in areas corresponding to the areas on which groups of the probe compounds are fixed, so that the corresponding areas of the stimulable phosphor sheet can absorb and store radiation energy of the radioactive label coming from the DNA fragments fixed to the DNA micro-array".

A representative configuration of the claimed radiation image storage panel of the invention is illustrated in Fig. 3 (i.e. "a DNA micro-array having a support and at least two defined areas"; see the "bringing" step of claim 1). For instance, note that the phosphor layer in Fig. 3 is placed in the form of dots on the support. Each dot of the phosphor layer is placed in the position corresponding to the area of the micro-array sheet so as to efficiently absorb radiation coming from the radioactively labeled sample DNA fragments attached to the probe compounds attached to the corresponding position of the micro-array sheet only. Also, see Fig. 2 in the drawings.

The radiation image storage panel having the claimed configuration, such as that illustrated in Fig. 2, "is almost free from noises [sic] caused by the inadvertently fixed non-complementary DNA fragments". See the specification at page 3, lines 6-8. This problem with "noise", as observed by the present inventors and as addressed by the claimed invention, is discussed on page 2, lines 26-35 of the specification.

The Examiner states on page 5 of the Office Action that Some et al. teach a process for detecting a complementary DNA fragment which includes a step of:

> "c) keeping the hybridized DNA in contact with a radiation image storage panel containing a stimulable phosphor in areas corresponding to the areas on which groups of DNAs are hybridized, so that the corresponding areas of the stimulable phosphor sheet can absorb and store radiation energy of the radioactive label coming from the fixed DNA fragments through the openings (Figures 1 and 8 and Column 7, lines 43-50);"

The above quotation highlights the Examiner's misunderstanding of the present invention vis-à-vis the prior art. Each of the Some et al. Figs. 1 and 8 show a radiation image storage panel with a sample sheet. See ref. Num. 1 of Fig. 1 and ref. Num. 15 of Fig. 8. The Examiner should further note that there are no dotted stimulable phosphor layers illustrated in the cited prior art.

Moreover, the description referred to by the Examiner at col. 7, lines 43-50 of the Some et al. reference reads as follows:

> The thus obtained transfer support and the stimulable phosphor sheet 1 are placed in layers for a certain period of time to expose the stimulable phosphor sheet 1 and at least a part of radiation emitted from the radioactively labeled substance on the transfer support is absorbed in the stimulable phosphor sheet 1, whereby the locational information regarding the radioactively labeled substance in the specimen is stored in the stimulable phosphor sheet 1.

The Examiner should especially note that "at least a part of radiation is absorbed in the stimulable phosphor sheet" means "some of radiation advances not towards the stimulable phosphor sheet and therefore is not absorbed in the stimulable phosphor sheet".

Accordingly, the cited Some et al. reference is completely silent with respect to the characteristic feature of the claimed process utilizing the claimed radiation image storage panel.

The Examiner should further note that the radioactively labeled DNA fragments in the cited Some et al. reference are fixed by hybridization to the DNA fragments separated and distributed on a gel support medium by means of electrophoresis (see col. 7, lines 21-24). Apparently, the positions of DNA fragments separated and distributed by electrophoresis are not determined before the autoradiographic process. Therefore, the image forming process of the cited Some et al. reference is not able to produce a stimulable phosphor sheet, that is, a radiation image storage panel, having a dotted phosphor layer in the areas corresponding to the electrophoresed DNA fragment bands.

Accordingly, it is clear that the claimed radiation image storage panel having the dotted stimulable phosphor layers (i.e.

"a DNA micro-array having a support and at least two defined areas") is neither disclosed nor suggested in the Some et al. reference. Therefore, the Some et al. reference does not anticipate the present invention. Thus, reconsideration and withdrawal of the rejection of claims 1-3 under 35 U.S.C. 102(e) over the Some et al. reference is respectfully requested.

The secondary prior art references, namely, Linsley et al. and Ward et al. are completely silent with respect to the above-mentioned characteristic features of the present invention. Therefore, the Examiner has not established a prima facie case of obviousness since the prior art does not disclose or suggest the claimed missing limitations. Accordingly, the claimed invention is neither anticipated nor obvious over the teaching of the cited prior art references.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three month extension of time for filing a response in connection with the present application. The required fee of $920.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By _____

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